1.2 Prevention of Postoperative Nausea and/or Vomiting

Ondansetron Injection, USP is approved for patients aged 6 months and older. Ondansetron injection should not be mixed with solutions for which physical and chemical compatibility have not been established. Sodium Chloride Injection, 5% Dextrose and 0.45% Sodium Chloride Injection, and 3% Sodium Chloride Injection.

4 CONTRAINDICATIONS

- Hyperkalemia
- Hypokalemia
- Hypomagnesemia
- Hypocalcemia

5 WARNINGS AND PRECAUTIONS

- Cardiac arrhythmias
- QTc interval prolongation
- Neurological events
- Seizures
- Severe cutaneous reactions
- Interactions with other drugs

8.5 Hepatic Impairment

8.7 Pregnancy

9 DRUG ABUSE AND DEPENDENCE

12 CLINICAL PHARMACOLOGY

12.1 Absorption

12.2 Distribution

12.3 Pharmacokinetics

13 ADVERSE REACTIONS

14 NON CLINICAL TOXICOLOGY

Pregnancy Category B. Reproduction studies have been performed in pregnant rats and rabbits at intravenous doses up to 30 times the maximum recommended human daily dose and have revealed no evidence of harm to the fetus due to ondansetron. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

16 HOW SUPPLIED/STORAGE AND HANDLING

Ondansetron injection is supplied as a sterile lyophilized powder for reconstitution to the 8 mg/mL and 16 mg/mL concentrations in a 10 mL vial. The vials are supplied in the following packages:

- 4 mg/2 mL & 40 mg/20 mL
- 8 mg/2 mL & 80 mg/20 mL
- 16 mg/2 mL & 160 mg/20 mL

The vials are packaged in cartons of 10

- 4 mg/2 mL & 40 mg/20 mL
- 8 mg/2 mL & 80 mg/20 mL
- 16 mg/2 mL & 160 mg/20 mL

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Keep the vials in the carton until time of use.